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DEPARTMENT OF JUSTICE
Drug Enforcement Administration

Vincent G. Colosimo, D.M.D.
Decision and Order

On February 27, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Vincent G. Colosimo, D.M.D. (hereinafter, Applicant). GX 1. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration as a practitioner, on the ground that his "registration would be inconsistent with the public interest." Id. at 1 (citing 21 U.S.C. 823(f)).

More specifically, the Show Cause Order alleged that on November 5, 2009, Applicant had surrendered his previous DEA registration, and that on June 20, 2012, Applicant had applied for a new registration at the proposed registered location of Dental Village, 7117 East Broadway Blvd., Tucson, Arizona.[1] Id. The Show Cause Order then alleged that on September 8, 2000, DEA Investigators (DIs) had conducted an inspection of Applicant's then-registered location, during which the DIs found approximately 108 dosage units of 7.5/500mg Lortab and 400 dosage units of diazepam 10mg, and that Applicant "told investigators that [he] transported the controlled substances to [his] place of practice in order to dispense [them] to [his] patients before and after procedures," as well as that he had "consumed several dosage units of [the] diazepam . . . upon the recommendation of his physician." Id. at 1-2.

Next, the Show Cause Order alleged that on January 28, 2010, the United States Attorney for the Western District of Pennsylvania charged Applicant with "knowingly, intentionally, and

[1] Applicant initially applied for registration at a different address. However, several weeks before the Show Cause Order was issued, he changed the address of his proposed registered location to Dental Village. GX 15.

unlawfully conspiring to distribute and possess with intent to distribute 500 grams or more of a mixture and substance containing a detectable amount of cocaine, a Schedule II" controlled substance. Id. at 2 (citing 21 U.S.C. 846). The Order then alleged that Applicant pled guilty to the charge, and that on July 6, 2010, the U.S. District Court for the Western District of Pennsylvania convicted him of the charge. Id.

Finally, the Show Cause Order alleged that various state dental boards had taken action against his dental licenses based on his conviction. Id. The Show Cause Order alleged that these included the Pennsylvania State Board of Dentistry, which suspended his license for five years; the Nevada Board of Dental Examiners, with which he had entered a stipulation, pursuant to which he voluntarily surrendered his Nevada license; and the Arizona State Board of Dental Examiners, which on August 12, 2010, suspended his dental license for five years. Id. The Order then alleged that on June 11, 2012, Applicant entered into an agreement with the Arizona Board, pursuant to which he "agreed to enroll in a treatment and rehabilitation program and complete 36 hours of continuing education in . . . substance abuse," and was granted a conditional license. Id.

On March 4, 2013, the Show Cause Order was served on Applicant by Certified Mail. GX 2. On April 4, 2013, Applicant's letter requesting a hearing (which had been mailed) was received by the Office of Administrative Law Judges. GX 4, at 2. Deeming the request to be one day late, the ALJ ordered the Parties to file a statement addressing whether there was good cause to excuse the late filing. GX 3. Both Parties filed such statements; the Government also filed a motion to terminate the proceedings. GX 5. Thereafter, the ALJ granted the Government's motion, finding that Applicant had not demonstrated good cause and terminated the hearing.

Thereafter, the Government filed a Request for Final Agency Action. On review, the Administrator vacated the ALJ's order terminating the proceeding and rejected the Government's request for final agency action. While noting that Applicant had not supported with affidavits the various factual assertions made by him in response to the ALJ's order, which directed the parties to address whether there was good cause to excuse the untimely filing, the Administrator held that if those assertions were supported, Applicant had demonstrated good cause. The Administrator further noted that while the Applicant's hearing "request was not received by the Hearing Clerk until the afternoon of April 4, 2013, the Show Cause Order instructed [him] to mail his hearing request to an address which is a different physical location than the Office of the Administrative Law Judges" and that the record did not "establish whether [the] hearing request was received by the former on the same day that it was received by the hearing clerk." Administrator's Order (GX 16), at 5 n.3. The Administrator further explained that "any delay that is attributable to a delay in the delivery of mail within the Agency is not properly chargeable to" Applicant. Id. The Administrator thus remanded the case to the Office of Administrative Law Judges for further proceedings consistent with her order. Id.

On remand, the ALJ ordered the parties to file their prehearing statements and to serve a copy of their proposed exhibits by certain dates. ALJ Ex. 10. While the Government timely complied with the ALJ's order, ALJ Ex. 11, Applicant did not. Tr. 9-10; 14-15 (Nov. 19, 2013). The Government then moved to terminate the proceeding, on the ground that Applicant had waived his right to a hearing. ALJ Ex. 12, at 2 (citing cases).

Thereafter, the ALJ held the initial day of the hearing, during which he found that Applicant had not established good cause for failing to file his prehearing statement and barred him from subsequently introducing witness testimony as well as documentary evidence. GX 18,

at 2. The following day, the ALJ issued an order setting the date for the evidentiary phase of the hearing. Id. However, six days before the hearing was to reconvene, Applicant's counsel contacted the ALJ's office and suggested that Applicant would seek to withdraw his application. Id. The ALJ then scheduled a Prehearing Conference for the purpose of determining whether there was any need to conduct the evidentiary phase of the hearing. Id.

The next day, Respondent filed a motion to withdraw his application stating that he "does not wish to proceed with a hearing where the DEA participates." GX 17, at 3. At the Prehearing Conference, the Government's counsel explained that the ALJ did not have authority to rule on Respondent's motion to withdraw but could grant a request to waive his right to a hearing. GX 18, at 1; see 21 CFR 1301.16. The ALJ then asked Respondent's counsel "whether Respondent wished to withdraw his application or whether he wished to waive his right to a hearing." GX 18, at 2. Respondent's counsel answered that Respondent wanted to do both, but even if the ALJ lacked authority to grant Respondent's motion to withdraw his application, he "still wished to waive his right to a hearing." Id. The Government did not object to Respondent's request to waive his right to a hearing. Id.

Later that day, the ALJ issued an order in which he found that Respondent had "expressly waived his opportunity for a hearing." Id.[2] Regarding the motion to withdraw, the ALJ noted that under 21 CFR 1301.16, an applicant, who has been issued an order to show cause, may withdraw his application "with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest." The ALJ thus concluded that he was without authority to act on Respondent's withdrawal request.

[2] The order was entitled: "Order Vacating Part of Order Dated November 20, 2013 And Remanding Case To The Administrator For Final Disposition." ALJs do not, however, remand cases to the Administrator or Deputy Administrator. They either terminate a proceeding; or conduct a proceeding, prepare a recommended decision, and forward the record to the Administrator's Office for review.

While the ALJ provided that the parties could file an objection to his order, neither party did so, and on January 16, 2014, the ALJ forwarded the record of the proceeding to my Office.

On February 28, 2014, the Government filed a Request for Final Agency Action seeking the denial of Respondent's application "on the basis that [his] registration would be inconsistent with the public interest." Gov. Request for Final Agency Action, at 1. Therein, the Government states that the ALJ "forwarded the case to the Administrator for either approval of Respondent's request to withdraw his application or for Final Agency Action." Id. at 3. While the Government observes that Respondent has waived his right to a hearing, it does not address whether there is either "good cause" to grant Respondent's withdrawal request (which remains pending before me) or whether granting his request "is in the public interest." See id. at 1-9. I conclude, however, that granting Respondent's withdrawal request is in the public interest.

DISCUSSION

No decision of the Agency has squarely confronted the question of whether the granting of a request to withdraw an application, which is submitted by a person after he has been issued a show cause order, is in the public interest. However, in Liddy's Pharmacy, L.L.C., 76 FR 48887 (2011), the Administrator, in rejecting a motion by the Government to dismiss a case as moot, provided some guidance (albeit in dictum) as to when the granting of a withdrawal request, which is filed after the issuance of a show cause order, is in the public interest.

In Liddy's Pharmacy, the Government issued a show cause order, which sought the revocation of the respondent's registration on the ground that it had committed acts which render its registration inconsistent with the public interest, and proceeded to a hearing before an ALJ, at which it prevailed. 76 FR at 48888. While the matter was pending the Administrator's review, the respondent agreed to voluntarily surrender its registration and the Government moved to

terminate the proceeding on the ground that it had become moot. Id. The respondent, however, had previously filed a timely renewal application. Id. at 48888-89.

After noting that the voluntary surrender form "contain[ed] no language manifesting that [r]espondent ha[d] withdrawn its pending application," the Administrator explained that even if the respondent had requested to withdraw its application, she would have "concluded that allowing [r]espondent to withdraw its application would be contrary to the public interest." Id. at 48888. In reaching this conclusion, the Administrator noted several factors, including the "extensive resources that have been expended in both the litigation and review of this case, the egregious misconduct established by th[e] record," and that the respondent could immediately reapply for a new registration. Id. While the hearing in Liddy was not particularly lengthy (in part, because only the Government presented evidence), the record was nonetheless extensive.[3]

Of note, in Liddy, the Government was the party which moved to terminate the proceeding. Thus, the Administrator did not discuss the potential prejudice to the Government had she allowed the respondent to withdraw its application. However, it is manifest that where the Government has issued a show cause order to an applicant, the potential prejudice to the Government is an important factor which should be considered in determining whether to grant a motion to withdraw an application.

It is indisputable that Applicant's conduct in engaging in a criminal conspiracy to distribute, and possess with intent distribute, 500 grams or more of cocaine, is egregious misconduct. Moreover, no regulation bars Applicant from immediately reapplying for a

[3] A review of the Agency's decision in Liddy shows that the respondent had dispensed over 42,000 controlled substance prescriptions for millions of dosage units, which were written by physicians to patients who resided in States where the former were not licensed to practice medicine and with whom they had not established a valid doctor-patient relationship, and thus, were issued outside of the usual course of professional practice, in violation of 21 CFR 1306.04(a). Id. at 48893-96.

registration. I nonetheless hold, however, that the other factors support the conclusion that granting his withdrawal request in in the public interest.

Here, there has been no proceeding on the merits of the allegations and thus extensive resources have not been expended in the litigation and review of this case. Moreover, reviewing the allegations and the record submitted by the Government, I conclude that granting the withdrawal request will not prejudice the Government in the event Applicant reapplies in the future.

In this matter, the Government has proposed the denial of the application based on three sets of circumstances: (1) The alleged findings of an investigation conducted in 2000; (2) his 2010 conviction for violating 21 U.S.C. 846; and (3) the state board orders that were issued following his 2010 conviction. Id. at 6-8. However, in the event Applicant was to reapply, his conviction is not subject to relitigation in this proceeding and the Government can again rely on it as a basis to deny the application. See 21 U.S.C. 823(f)(3); Robert L. Dougherty, 76 FR 16823, 16830 (2011) (discussing Robert A. Leslie, 60 FR 14004, 14005 (1995); Robert A. Leslie, 64 FR 25908 (1999); and Robert A. Leslie, 68 FR 15227 (2003)). So too, the Government can rely on the state board orders, to the extent they add anything that is probative of whether granting a new application would be consistent with the public interest.

Indeed, the only potential prejudice that could accrue to the Government would be that with the passage of additional time, it would be unable to produce reliable evidence probative of the violations allegedly found in the investigation, which was conducted fourteen years ago, when Applicant was practicing in Pittsburgh, Pennsylvania. The Government cannot, however, claim prejudice, because the evidence it submitted with its Request for Final Agency Action to support the allegations does not rise to the level of substantial evidence. Here, the evidence on

these allegations was limited to an affidavit of a Diversion Investigator, with the Phoenix Office, who was assigned to the current matter in December 2012. While the DI's affidavit states that "[t]he matters contained in this declaration are based upon my personal knowledge, training, and experience," and then makes several factual assertions regarding the 2000 investigation, the affidavit does not establish that the DI was personally involved in that investigation. See DI's Declaration, at 1-3. Moreover, the affidavit does not cite any documentary evidence that supports these factual assertions and the investigative record submitted by the Government contains no such evidence. Thus, were I to proceed to the merits of the Government's Request for Final Agency Action, I would be required to conclude that these allegations are not supported by substantial evidence.

Accordingly, I conclude that granting Applicant's withdrawal request will not prejudice the Government. Moreover, while some agency resources have been expended in the review of this matter, this was occasioned by the need to set forth the factors to be considered in determining whether the granting of a withdrawal request, which is made after the issuance of a show cause order, "is in the public interest." 21 CFR 1301.16(a). Because I conclude that granting Applicant's request to withdraw his application "is in the public interest," I grant his request. And because there is no longer an application to act upon, I hold that this case is now moot and dismiss the Order to Show Cause.

It is so ordered.

Dated: April 4, 2014.

Thomas M. Harrigan,
Deputy Administrator.

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